IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Quality Management, Inc., Plaintiff, v. Tom W. Thurman, Inc. d/b/a BoldBio Tech., Inc., Defendant.	Civil Action No.: **JURY TRIAL DEMANDED** 6,845,676

COMPLAINT

Plaintiff, Quality Management, Inc. ("QMI"), for its Complaint against Defendant, Tom W. Thurman, Inc. d/b/a BoldBio Tech., Inc. ("Defendant") states and alleges as follows:

THE PARTIES

1. Plaintiff, Quality Management, Inc., is incorporated in the State of Minnesota and has a principal place of business at 426 Hayward Avenue North, Oakdale, Minnesota 55128.

2. Upon information and belief, Defendant is incorporated in the State of Texas and has a principal place of business at 19 Crenshaw Street, Amarillo, Texas 79124.

3. On January 25, 2005, United States Patent No. 6,845,676 ("the '676 patent") entitled "Continuous Fluid Sampler and Method" was issued to inventor Darrell

US006845676B2

(12) **United States Patent**
Bigalke

(10) **Patent No.: US 6,845,676 B2**
(45) **Date of Patent: Jan. 25, 2005**

(54) **CONTINUOUS FLUID SAMPLER AND METHOD**

(76) Inventor: **Darrell Lee Bigalke**, 11395 Irish Ave. North, Stillwater, MN (US) 55082

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **10/022,294**

(22) Filed: **Dec. 14, 2001**

(65) **Prior Publication Data**

US 2003/0110870 A1 Jun. 19, 2003

(51) **Int. Cl.**[7] **G01N 1/14**; G01N 1/20

(52) **U.S. Cl.** **73/863.85**; 73/863.03; 73/863.83; 73/863.86

(58) **Field of Search** 73/863.83–863.86, 73/863.03, 863.02, 864.34, 864.35

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,534,613 A * 10/1970 Traver et al. 73/863.85
3,776,042 A * 12/1973 Werra et al. 73/863.85
3,779,082 A * 12/1973 Galloway 73/863.85
4,785,676 A * 11/1988 DeOca et al. 73/863.85
4,941,517 A 7/1990 Galloway .... 73/863.85 X
5,049,492 A * 9/1991 Sauer et al. .... 73/863.85 X
5,086,813 A 2/1992 Galloway .... 73/863.85 X
5,119,473 A 6/1992 Ikenoue
5,269,350 A 12/1993 Galloway 141/1
5,296,197 A * 3/1994 Newberg et al. ..... 73/863.85 X
5,743,209 A 4/1998 Bazin et al. 119/14.08
5,803,078 A * 9/1998 Brauner 128/207.14
H1960 H * 6/2001 Conrad et al. 73/864.82

FOREIGN PATENT DOCUMENTS

WO WO 96/03859 2/1996 .... A01J/5/017
WO WO 00/33901 * 6/2000 .... 604/93

OTHER PUBLICATIONS

"Keofitt World Leaders in Sterile Sampling", 4 pages (date unknown), but by Dec. 13, 2001.
Liquid Sampling Systems, Inc., Cedar Rapids, IA, "The Pro-Rata™ Line Sampler, The future of dairy sampling–today", 4 pages, (date unknown), but by Dec. 13, 2001.
Tate, J.L., "The Art of Managing Contamination", *Pharmaceutical Processing*, 4 pages (Jan. 2000).

* cited by examiner

Primary Examiner—Thomas P. Noland
(74) *Attorney, Agent, or Firm*—Merchant & Gould P.C.

(57) **ABSTRACT**

An aseptic, continuous sampling arrangement used in a fluid transportation system, the arrangement including an elbow pipe and a septum cartridge. The sampling arrangement further including a needle, a tube, and a collection reservoir, arranged such that the collection reservoir is in fluid contact with the fluid transportation system. The sampling arrangement configured to create a non-laminar fluid flow region from which a continuous sample of fluid material is drawn.

16 Claims, 5 Drawing Sheets

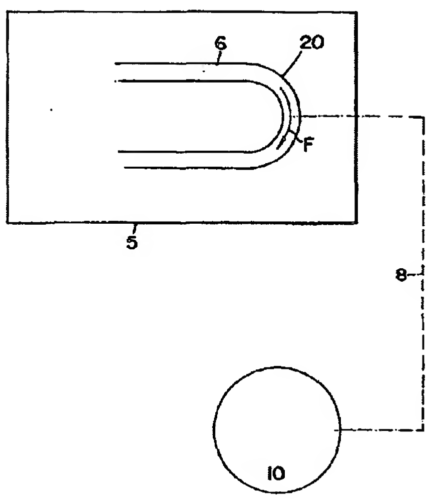
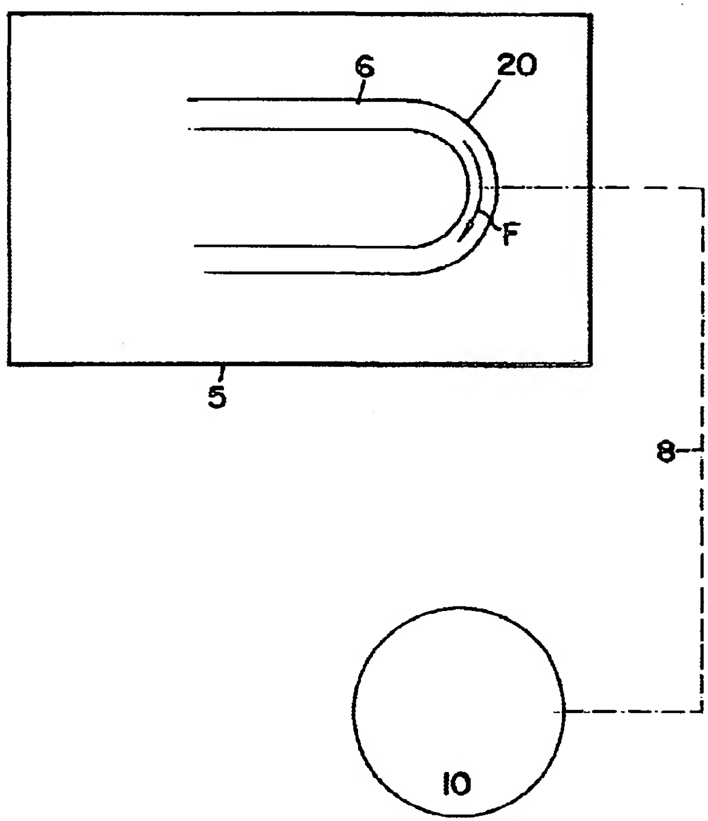


FIG. 1



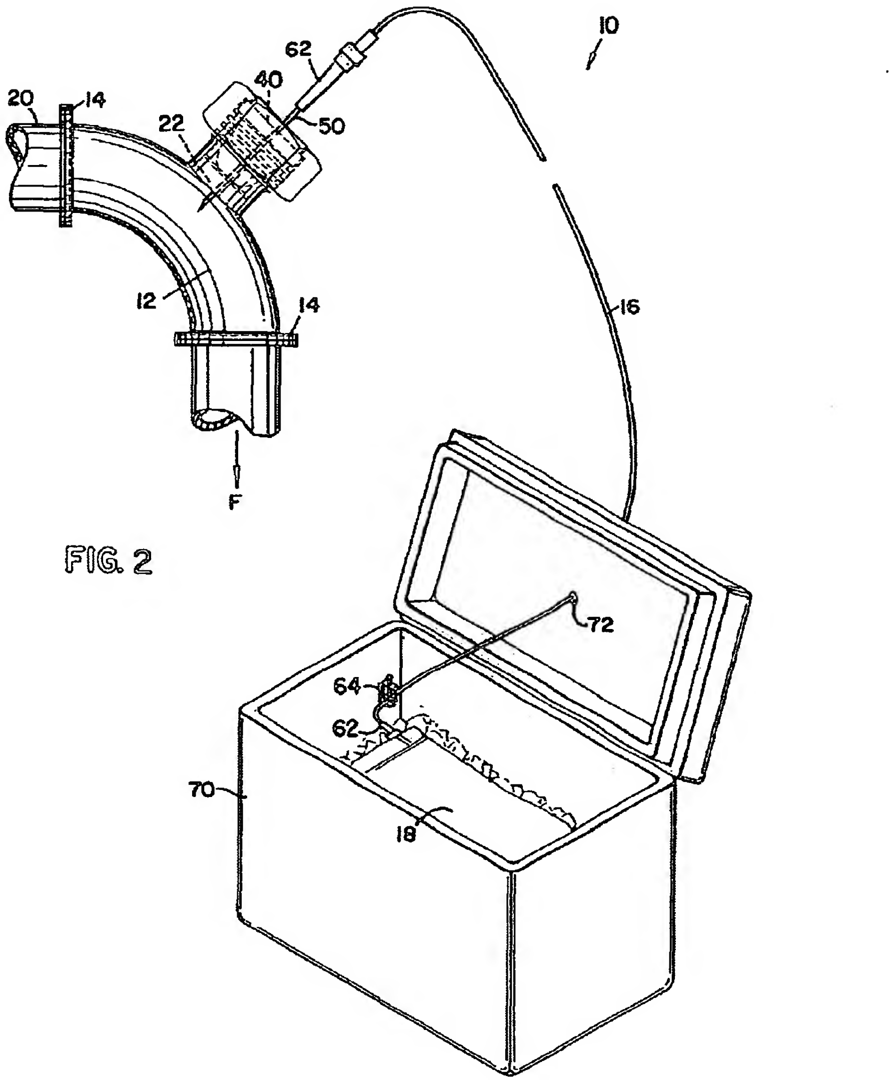
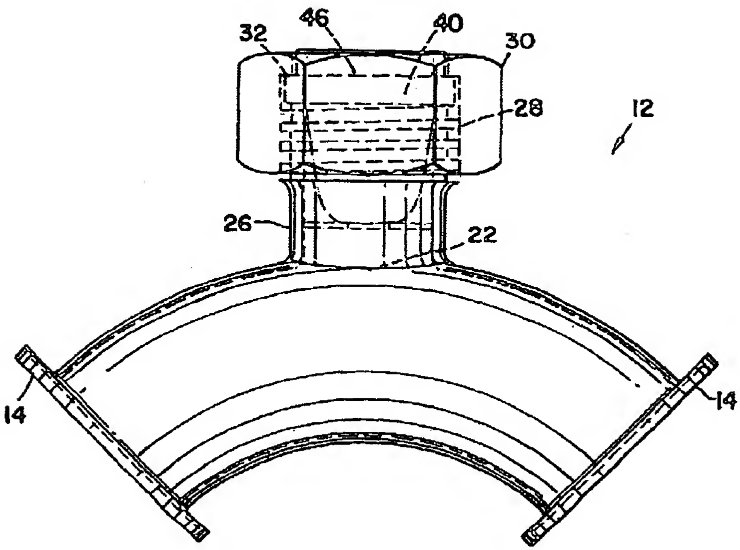


FIG. 2

FIG. 3



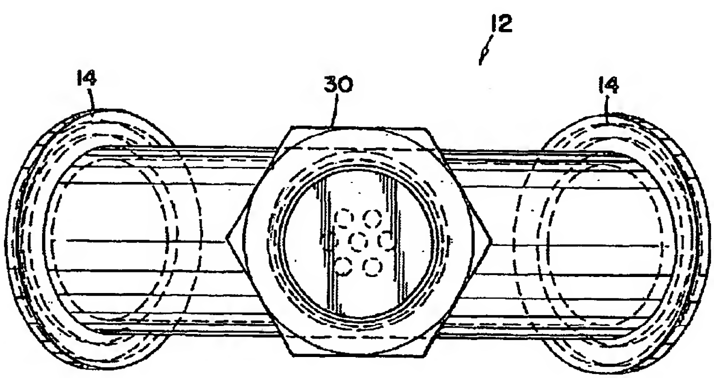


FIG. 4

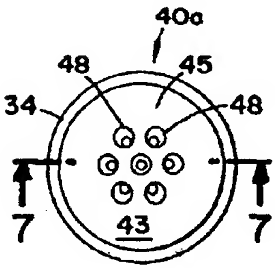


FIG. 5

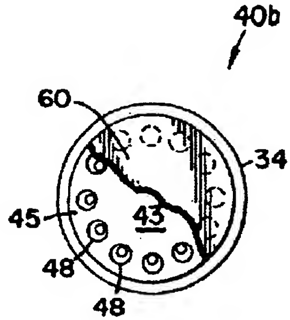


FIG. 6

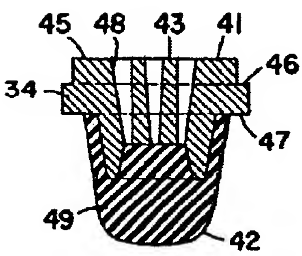


FIG. 7

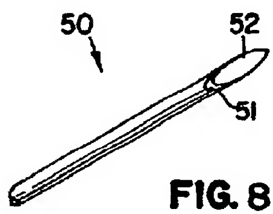
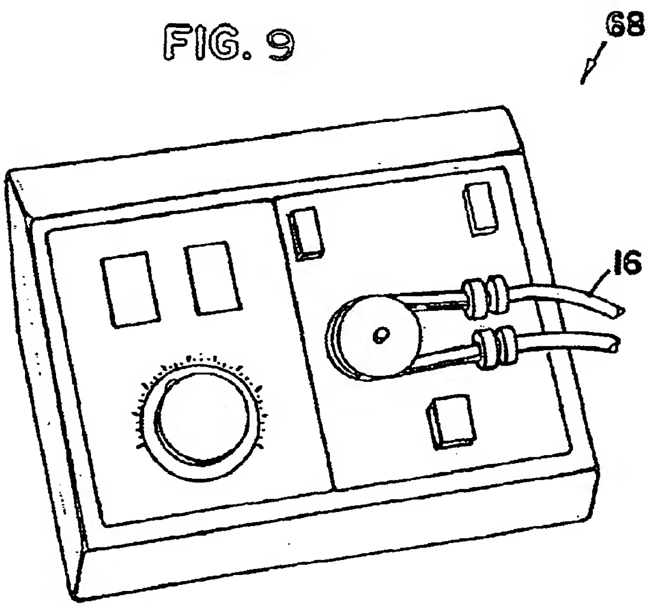


FIG. 8

FIG. 9



CONTINUOUS FLUID SAMPLER AND METHOD

FIELD OF THE INVENTION

This disclosure concerns a sampling arrangement. More specifically, this disclosure describes the assembly and method of use of a sampling arrangement for aseptic, continuous sampling of a fluid material.

BACKGROUND OF THE INVENTION

There are numerous applications wherein it is desirable to obtain discrete or continuous samples from fluid transportation systems or fluid processing enclosures. Enclosures and fluid transportation systems, as used herein, refer to any closed containment structure without respect to its size. Thus it includes such small enclosures such as cans that may be used in shipping starter bacteria from a culture lab. On the other end of the spectrum, it includes large tanks and associated pipelines, which may have capacities of several thousand gallons, such as are used in the dairy processing industry.

Efficient and effective techniques and apparatus for obtaining aseptic samples from such systems and enclosures, are particularly desirable. Examples of industries that require such aseptic sampling include, but are not limited to, the pharmaceutical, bioengineering/biotechnology, brewing/distilling, food processing and dairy processing industries. Applications for such samplings range broadly from process monitoring to laboratory and research applications. For example, sampling is commonly used on dairy farms for herd management or in regulated manufacturing facilities. The sampling is used to detect and control microbial contamination, spoilage microorganisms, food-borne illness, and environmental mastitis both within systems being sampled and externally of such systems. While preferred embodiments of this invention will be described with respect to its sampling use and application in the dairy industry, it will be understood that the invention is not to be construed as limited to use in that industry or to the application described, or to any limitations associated with the specifics of the components or methods disclosed with respect to such preferred embodiments.

Various methods and devices have been employed to perform sampling tasks. Typical sampling techniques commonly involve discrete or isolated sampling from a laminar portion of a fluid transport line. Typical such sampling systems and techniques that have been used in the dairy processing industry are described in U.S. Pat. Nos. 4,941,517; 5,086,813; and 5,269,350. To the extent that such patents may be used to assist the reader in understanding principles and examples of sampling apparatus and methods, they are herein incorporated by reference.

While the apparatus and techniques described in these patents are particularly applicable to systems designed to accommodate them, there also exists a need to perform sampling in existing enclosures and fluid transportation systems that have not been designed for sampling functions. Such systems typically require redesign or retrofitting to accommodate sampling functions. Such retrofitting can be expensive and/or difficult to achieve, can require significant system downtime in implementation of the sampling function and/or replacement of parts to maintain the system, or can lead to system degradation or contamination of the system being sampled. For example, one known method of discrete sampling of fluid involves inserting a needle through a sealing gasket located between connecting ends of pipelines of the fluid transportation system. Problems arises from this method as this method is not aseptic because the gasket becomes so perforated after repeated sampling that the gasket may lose its sealing integrity or introduce contaminants into the system though the perforations. This method requires that the gasket be replaced, which can become expensive both in labor costs and shut down costs.

There are many applications wherein it is desirable to obtain a continuous sample from fluid transportation systems or fluid processing enclosures. The discrete sampling methods typically extract a discrete sample size limited to the volume of a hypodermic needle and syringe. Typically the needle is inserted, fluid is drawn, and the needle is removed. It would be beneficial in some applications to have a system that could draw a continuous, controlled and constant sample volume over an extended period of time. A sampling device that facilitates this feature would also need to accommodate larger volume samples and a means to cool the sample during longer sampling time periods. While continuous sampling techniques have been tried, they have generally not been particularly effective, efficient or reliable in maintaining the aseptic condition of the system during the sampling interval.

Known discrete sampling techniques have not proven to be readily adaptable to continuous sampling techniques. For example, if the sample is taken from a region of laminar fluid flow, the sampling needle can create a venturi effect in the fluid flow being sampled, which can cause reverse flow siphoning from the collected sample and back into the sampled fluid. If such suction effect is disrupted by providing the sampling system with an air gap, the aseptic nature of the sampling system is compromised.

Improvement in methods and devices for sampling is needed, generally to better accommodate: ease of repeated continuous sampling of large volumes; structural integrity of fluid transport equipment; management of contamination; and convenience of continuous and controlled volume sampling. The present invention addresses these and other needs for continuous sampling of fluid transportation systems or fluid processing enclosures.

SUMMARY OF THE INVENTION

The present invention provides an efficient, effective and reliable assembly and method for aseptic continuous sampling of a fluid material. The principles of this invention can be simply implemented with readily available materials and techniques that enable application of the invention to sampling equipment of original design, as well as to relatively simple and inexpensive retrofitting of existing fluid enclosures or fluid transportation systems. The principles of this invention can readily be implemented in kit form for retrofitting applications. Further, replacement of expendable parts for maintaining the sampling system can be readily and inexpensively achieved without costly system down time and by minimizing contamination to the sampled system.

In one aspect of the invention, the disclosure describes a continuous sampling arrangement including a collection container, a connecting conduit in closed fluid communication with the collection container, a collector in fluid communication with the connecting conduit, a pipe elbow having an aperture, and a septum positioned within the pipe aperture. The septum is constructed to provide for penetration of the needle to facilitate fluid communication between the pipe elbow and the collection container.

In another aspect of the invention, the disclosure describes a continuous sampling arrangement configured to

create a non-laminar flow area from which a continuous sample is drawn. A septum is placed adjacent the non-laminar flow area to facilitate penetration of a needle into the non-laminar flow area and provide fluid communication between the non-laminar flow area and a collection container.

In yet another aspect, a method for aseptic continuous sampling is disclosed wherein the principles described herein in a variety of embodiments are used in aseptic processes of sampling fluids.

In still another aspect, the invention relates to a kit that retrofits to existing fluid transportation systems or enclosures to permit aseptic continuous sampling according to the principles disclosed.

BRIEF DESCRIPTION OF THE DRAWINGS

Referring to the drawings wherein like numerals represent like parts throughout the several views,

FIG. 1 is a schematic illustration of a system incorporating a continuous sampling arrangement in accordance with the principles disclosed;

FIG. 2 is a detailed schematic illustration of one embodiment of the continuous sampling arrangement in accordance with the principles disclosed;

FIG. 3 is a side view of a pipe elbow depicted in the sampling arrangement of FIG. 2;

FIG. 4 is a top view of the pipe elbow depicted in FIG. 3;

FIG. 5 is a top view of one embodiment of a septum used in the sampling arrangement of FIG. 2;

FIG. 6 is a top fractional view of another embodiment of a septum used in the sampling arrangement of FIG. 2;

FIG. 7 is a cross sectional view of the septum shown in FIG. 5, taken generally along line 7—7 of FIG. 5;

FIG. 8 is a fragmentary perspective view of a needle depicted in the sampling arrangement of FIG. 2; and

FIG. 9 is an illustration of one embodiment of a regulating device that can be used in the sampling arrangement of the present invention.

DETAILED DESCRIPTION

This invention provides an apparatus and method for the continuous aseptic sampling of fluid material from a fluid transportation system or fluid processing enclosure 5, schematically illustrated in FIG. 1. A fluid material 6 to be sampled is illustrated as flowing through a fluid line 20 by the fluid flow arrow designation "F". A preferred sampling arrangement of the present invention is schematically illustrated at 10 and is depicted as operatively connected, by the dashed line 8, to sample the fluid material 6 (as hereinafter described in more detail).

The principles described herein for the sampling arrangement 10 can be used in various industries and in various applications where aseptic sampling of material is desired. Aseptic sampling involves transferring fluids to or from process systems that are sensitive to contamination from the outside environment. For example, the pharmaceutical, bioengineering/biotechnology, brewing/distilling, food processing and dairy processing industries are in need of aseptic sampling technology. Such sampling technology can be applied broadly, the applications ranging from process monitoring to laboratory and research applications. For example, the fluid processing enclosure or fluid transportation system 5 illustrated in FIG. 1 may comprise a dairy processing system used in the dairy industry. An example of one type of fluid processing enclosure or fluid transportation system 5 that has been used in the dairy processing industry is described in U.S. Pat. No. 5,269,350 and herein incorporated by reference. In such a system, the fluid material 6 therein may include raw milk or a processed milk product. The sampling arrangement 10 may be incorporated or retrofitted to the fluid transportation system 5 to provide continuous aseptic sampling for detecting microbial contamination or monitoring mastitis, coliform, food-borne illness bacteria, or spoilage bacteria in a dairy herd, for example.

While preferred embodiments of this invention will be described with respect to its sampling use and application in the dairy industry, it will be understood that the invention is not to be construed as limited to use in that industry or to the particular application described.

The Structural Components, Generally.

Referring to FIG. 2, the preferred sampling arrangement 10 depicted includes: an elbow 12 having flanges 14 and a port 22; a least one septum or septum cartridge 40 (shown in phantom); a connecting conduit 16; and a collection container 18. In general, the sampling arrangement 10 comprises an arrangement that provides for a continuous draw of fluid from a flow F within a fluid line 20, and deposits the fluid sample in the collection container 18 to provide the user with an accumulated process sample. It is to be understood that the fluid line 20 may comprise a variety of fluid transportation systems or fluid containment enclosures, and is not limited to pipe constructions. The collection container 18 may include a pouch, bag, reservoir, or other closed container of a typical construction and size, such as those used in the medical industry. In the illustrated embodiment, a medical type bag comprising a 2-liter collection pouch or bag is used. A variety of sizes and constructions of containers is contemplated.

As illustrated, the pipe segment or elbow 12 of the sampling arrangement 10 is in direct fluid communication with the fluid line 20 of the fluid transportation system. In accordance with the principles of the present invention, it is desirable to perform sampling from an area or region of non-laminar flow within the line 20. The elbow 12 provides a turbulent or non-laminar flow region within its interior flow cavity by its non-linear configuration. It is to be understood that there are other means of creating a non-laminar flow region within the fluid flow line, such as having a protrusion or device extending into the flowing fluid within a substantially straight portion of the fluid line. Therein fluid turbulence or non-laminar flow is formed downstream of the extending device or protrusion. Creation of a non-laminar sampling region eliminates the problem of reversed fluid flow from the sample to the main fluid line, which commonly occurs in devices and methods of the prior art.

Referring now to FIGS. 3 and 4, the connection flanges 14 of the elbow 12 extend circumferentially at each end of the elbow 12. The flanges 14 may include grooves (shown in phantom) sized to receive sealing gaskets (not shown) to seal the connections between pipe segments when installed in common fluid transportation line systems. In accord with the principles of the present invention, the sampling arrangement is generally adapted to be retrofit within existing fluid lines of various fluid flow systems 5 (FIG. 1). Certainly the sampling arrangement 10 can be incorporated as original equipment into new installations of fluid transportation lines as well. Other means of connection or retrofit adaptation, including welding, are contemplated as a means of installation. The sampling arrangement is generally designed with standard plumbing components to facilitate retrofit modifi-

cations. It is to be understood that non-standard elements, such as non-standard pipe diameter, fittings, or material, are within the scope of the principles disclosed.

Preferably the elbow **12** is made of industry standard stainless steel, such as 304 or 316L stainless steel. Other materials applicable for use in the industry into which the sampling arrangement is implemented are contemplated. The elbow depicted in FIG. **3** incorporates a standard 90-degree elbow. The angular configuration of the elbow will typically be a standard dimension within the range of 35 degrees to 180 degrees, typically 90 degrees. The preferred diameter of the elbow pipe is at least 1 inch, typically from about 1.5 to 3.5 inches in diameter.

The elbow **12** according to the present invention includes at least one aperture or port **22**. The elbow **12** may be located in any configuration in the fluid transportation system where the port **22** is operably in fluid communication with the fluid material **6** within the system. Thus, the interior angle of the elbow **12** may be oriented, for example, upward, downward or sideways in a fluid line arrangement. It is also contemplated that to ensure that the port is operably in fluid communication with the fluid material **6**, the port **22** may be configured in alternative locations on the elbow **12**. In the illustrated embodiment, the port **22** is located on the outer radius of the elbow **12**. Alternative embodiments may include, for example, an elbow having a port located on the interior radius of the elbow. Preferably, the port **22** is disposed at or within a non-laminar flow region of the elbow **12**.

As depicted in FIG. **3**, the port **22** may include a transversely extending pipe portion or conduit **26**. The conduit **26** is sized to receive a septum cartridge **40**. The conduit **26** may include an externally threaded region **28** for purposes of securing the septum cartridge **40**. In one embodiment, the thread comprises a standard 1.5"-8 ACME thread corresponding to a mating internally threaded nut **30**. The threaded nut **30** may include an internal annular shoulder **32** (shown in phantom). The annular shoulder **32** acts as a bearing surface that engages a first surface **46** of the septum cartridge **40** (shown also in FIG. **7**) to secure the septum cartridge in sealing manner when assembled within the port **22**. Other types of fasteners commonly used as securing or retaining means within this context are contemplated and may include, for example, a hex nut, a knurled lock nut, or a keyed nut.

Referring generally to FIG. **2**, the septum cartridge **40** is in fluid communication with the interior cavity of the fluid line **20** by means of the aperture or port **22** in the elbow **12**. As shown in FIGS. **5–7**, the septum cartridge **40** generally comprises a cap **45**, a central core member or boot **49**, and a plurality of guide holes **48** formed through the cap. For purposes of clarifying features, the septum cartridge **40** can be considered to have a top **41** and a bottom **42**.

The cross-section of the boot **49** is seen to increase progressively from the bottom **42** toward the top **41** of the septum cartridge **40**. The boot **49** is sized such that when the boot is placed within the port **22** of the elbow there is compressive contact between the interior surfaces defining the port **22** and the boot **49**. The boot thereby functions as a sealing member. The boot **49** illustrated is generally conical, but could adopt a variety of shapes as will be obvious from the following discussion of the functioning of the septum cartridge in combination with other components of the invention.

The boot **49** may be made of material that is generally considered to be of a rubber compound. While compounding of an acceptable rubber composition is believed to be within the skill of the rubber molding art, it is found that rubber compounds based on ethylene propylene diene monomer terpolymer (EPDM) are particularly advantageous, having suitable sealing characteristics. EPDM is a known elastomer, and recognized by those skilled in the polymer arts. Other elastomers are contemplated, such as those derived from, or modified with, butene isoprene, ethylene, and the like. In an alternative embodiment, the boot may comprise a silicon compound. Silicon also provides suitable sealing characteristics. Materials such as Viton or other FDA approved elastomers are also contemplated for use in manufacture of the boot.

Preferably, the cap **45** includes an annular radially extending portion **34** defining the first upwardly oriented surface **46** and an opposing second lower surface **47**. The outer diameter of the annular portion **34** is preferably only slightly less than the inner diameter of the internal shoulder **32** on the threaded nut **30** for purposes of engaging and retaining the septum cartridge **40** within the port **22** of the elbow in the sampling arrangement **10**.

The cap **45** is made of a material that is normally not penetrable by conventional hypodermic needles. A typical material for fabrication of the cap may include one of the engineering plastics, such as nylon, polypropylene, or high-density polyethylene. The penetrability of the septum cartridge **40** is thus provided by one or more of the integrally formed guide holes **48**, which begin from a top surface **43** of the cap **45** and extend downwardly through the cap **45**.

The guide holes **48** are integral with the cap **45** and located to correspond to the boot **49**. The guide holes **48** extend downwardly through the cap structure **45** and are oriented and positioned so that a sampling needle **50** (shown in FIG. **8**) may pass through the guide hole **48** and into the boot **49**. The guide holes **48** are generally sized to be only slightly larger than the needle, such that the needle slidably fits snugly within the guide hole, preferably without substantial friction, but with a close enough fit to ensure that the guide hole provides direction to the needle as it is inserted through the boot. In one embodiment (FIG. **5**), the septum cartridge **40*a*** includes seven guide holes. In another embodiment (FIG. **6**), the septum cartridge **40*b*** includes twelve guide holes. Typically the septum cartridge includes at least one guide hole, generally 1 to 15 guide holes.

A cover film **60** covers the top surface **43** of the cap **45**, including the guide holes **48** formed in the top surface **43** of the cap **45**. The cover film **60** easily identifies used holes to reduce the risk of contamination from reinserting a needle into a previously used guide hole. The cover film **60** may be made from any readily pierceable film material. A typical film material is a vinyl tape having an adhesive coating to securably attach the cover film **60** to the top surface of the cap **45**.

Referring to FIGS. **2** and **8**, the penetrating body or needle **50** is in fluid communication with the connecting conduit **16**, and the connecting conduit **16** is in fluid communication with the collection container **18**. In the preferred embodiment, the needle comprises a beveled end **51** having an aperture **52** that defines a hollow portion running longitudinally through the needle **50**. It is to be understood that other penetrating bodies, such as lumens, hollow members, or inserting devices may be used in accordance with the principles disclosed.

In use, the needle **50** penetrates the cover **60**, passes through a selected guide hole **48**, and penetrates through the boot **49**. As the needle penetrates the boot, the needle displaces the elastomeric/rubber material of the boot which forms a fluid impenetrable seal about the needle. The

beveled end **51** of the needle **50** progresses through the boot **49** and emerges from the boot at the bottom **42** of the septum cartridge **40**. The needle therein enters into the flow of fluid F.

The needle **50** is sized and adapted for use with the septum cartridge **40**. Typically the needle comprises a 12 gauge to 22 gauge needle, preferably a 16 gauge needle. The needle generally has a length of from about 1.0 inches to 4.5 inches. Preferably the needle is at least 1.5 inches in length if the port **22** is bottom placement oriented and at least 2.0 inches if the port **22** is top placement oriented. What is meant by top and bottom placement oriented is how the sampling port is oriented with respect to ground. Thus, if the elbow is top placement oriented, a longer needle **50** is needed to ensure the needle aperture **52** is submerged within the fluid material when operatively inserted through the septum **40**.

Still referring to FIG. **2**, the connecting conduit **16** also includes sealing ends **62** at locations where the fluid flow transitions from the needle **50** to the connecting conduit **16** and from the connecting conduit **16** to the collection container **18**. A typical, usable connecting conduit is the type used by the medical industry in fluid administration sets. Conduit in accordance with the principles disclosed includes, for example, tubing, flexible piping or flexible lumen constructions that provide closed, aseptic fluid communication between ends.

Preferably the connecting conduit **16** is of sufficient length to reach from the elbow **12** to an area where the collection container **18** is placed. The length may thus vary and typically falls within the range of 5 inches to 65 inches, and preferably is about 38 inches in length. In one embodiment, the connecting conduit comprises a 0.121 inch inside diameter and a 0.166 outside diameter. It is to be understood that typical fluid administration sets having a needle, connecting conduit, and a collection pouch are contemplated for use in this sampling arrangement.

In use, the needle **50** is inserted through the septum **40** into a non-laminar fluid flow region of the elbow **12**. Sampling at a non-laminar fluid flow region addresses the problem of reversed fluid flow often created by a venturi effect of prior sampling systems. The venturi effect is created where the velocity of the laminar fluid flow flowing past an orifice or tube opening (such as in a needle) causes a corresponding decrease in fluid pressure, which creates a siphoning or suction. Thus, instead of drawing sampled fluid from the fluid line into a collection container, sampled fluid is actually drawn from the collection container back into the fluid line. The sampling arrangement **10** of the present invention reduces or eliminates this problem.

Some Selected Alternate Embodiments

Alternative embodiments incorporating the principles of the present invention will be apparent from the description below and in the context of the illustrations in FIGS. **2** and **9**.

In one alternative embodiment, the sampling arrangement **10** includes a flow restricting device. The flow restricting device may comprise a clamp **64** as shown in FIG. **2**. The clamp **64** compressively engages the outer surface of the connecting conduit **16** and is adjustable such that flow through the tube may be restricted to a desired flow rate. Thereby, the continuous sampling rate may be increased or decreased during sampling as needed.

Another embodiment of the sampling arrangement includes an alternative means of regulating flow. FIG. **9** depicts a fragmented portion of a sampling arrangement including a metering or peristaltic pump **68**. The peristaltic

pump **68** cooperatively engages connecting conduit **16** and is adjusted as is known in the art to provide a desired regulated flow rate.

The clamp **64** and the peristaltic pump **68** are products of common manufacture. The clamp may comprise any clamping device suitable to provide restriction in the connecting conduit **16**. The peristaltic pump may comprise, for example, a variable flow pump having a medium flow rate of 4.0 to 85.0 milliliters per minute. Specifically, a Medium Flow variable flow pump, Model Number 54856-075, manufactured by MASTERFLEX is one variable flow pump that may be used.

Yet another embodiment of the present invention provides for cooling of the extracted sample held by the collection container. If it is desirable to keep the extracted sample cool during collection, the collection container **18** may be placed in an insulated cooler **70** surrounded by ice or cold packs as shown in FIG. **1**, for example. Common coolers can be modified to include a hole **72** in the top or lid through which the connecting conduit **16** can be routed.

The alternative embodiments herein described may be used in combination with each other or used independent of one another.

The Method of Continuous Sampling, Generally.

In operation, the elbow **12** is installed at a convenient sampling location along a fluid line **20**. The elbow is preferably oriented such that the port **22** is in direct fluid contact with the material transferred within the fluid line, to reduce the potential of air drawn during sampling.

The boot **49** of the septum cartridge **40** is placed into the sampling port **22** until the second surface **47** of the cap **45** rests against the outer edge of the sampling port **22**. The securing nut **30** is installed onto the conduit of the port **22** to sealingly, operatively secure the septum within the port.

For aseptic sampling, the sampling arrangement, including the port, nut, septum cartridge, etc, are sanitized with a common alcohol prep or other sanitizer. In particular, aseptic sampling is optimized when the cover film **60** is cleansed with a disinfectant, and a sterilized needle **50** is inserted through the disinfected cover film, through an unused guide hole, and through the septum boot.

The needle is preferably directed or slanted toward the center of the septum boot at insertion. This provides greater assurance that the needle penetrates through the entirety of the boot. In effect, the boot essentially squeegees or cleanses the needle of any contaminants missed during initial aseptic disinfectant processes. Directing the needle toward the center of the boot also reduces the possibility of contacting the wall of the extended portion of the elbow.

The needle may be oriented such that the beveled end **51** faces toward the flow of the fluid material to aid in fluid sampling. A pressure differential is applied between the collection container and the fluid line to effect the fluid sampling or material transfer. The pressure differential maybe applied in a number of ways. One way is by introducing pressure into the fluid line. Another is by reducing pressure in the connecting conduit or collection container. Any means of generating an adequate pressure differential between the fluid line and the collection container is effective to cause the flow of material through the needle. Other methods of applying the pressure differential and thus effecting the transfer of a sample will be obvious to those skilled in the art.

Material from a tank, for example, thus flows from the fluid line **20**, through the needle **50**, and into the collection container **18** by way of the connecting conduit **16**. In one alternative application, the collection container may be

Lee Bigalke. Mr. Bigalke subsequently assigned the '676 patent to QMI. A copy of the '676 patent is attached as Exhibit A. The '676 patent is currently owned by QMI.

4. On May 16, 2006, United States Patent No. 7,044,010 ("the '010 patent") entitled "Continuous Fluid Sampler and Method" was issued to inventor Darrell Lee Bigalke. Mr. Bigalke subsequently assigned the '010 patent to QMI. A copy of the '010 patent is attached as Exhibit B. The '010 patent is currently owned by QMI.

5. QMI is in the business of designing, manufacturing, distributing, and selling products in interstate commerce, including sales in the State of Minnesota.

6. QMI designs, manufactures, distributes, and sells systems for the aseptic sampling of liquid processes.

7. Defendant is in the business of distributing and selling products in interstate commerce, including in Minnesota.

JURISDICTION AND VENUE

8. This is a claim for inducing patent infringement arising under the Acts of Congress relating to patents, 35 U.S.C. §§ 271 and 282-85.

9. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) (an action arising under an Act of Congress relating to patents).

10. Defendant is subject to personal jurisdiction in this Judicial District by virtue of the fact that (1) it has sold products that infringe the patent-in-suit in this Judicial District and in judicial districts throughout the United States, (2) it operates a website (http://www.boldbiotech.com) that is accessible to residents of this Judicial District and that invites visitors to inquire regarding purchasing Defendant products, (3) it

placed into a cooling container **70** of ice or ice water, for example, to reduce or eliminate bacterial growth during the sampling process.

The flow from the fluid line **20** to the collection container **18** may be adjusted to a particular flow or sampling rate by means of the clamp restriction. The flow may likewise be metered wherein the peristaltic pump is assembled to the connecting conduit to regulate the flow.

When the desired sample has been collected, the collection container is removed from the connecting conduit **16** and sealed. The needle **50** is removed from the septum cartridge **40**. As the needle end is withdrawn, the material of the boot **49** withdraws into the position held prior to needle penetration. The boot **49** of the septum **40** thus closes and seals the passageway of the now removed needle.

After performing a number of sampling procedures, so that all guide holes have been used, the septum cartridge **40** is removed and discarded. The punctured cover film **60** provides a ready indictor of those guide holes that have been used. A new septum cartridge easily replaces the used septum cartridge for future samplings.

The above specification, examples and data provide a complete description of the manufacture and use of the invention. Many embodiments of the invention can be made according to the disclosed principles.

I claim:

1. A continuous sampling arrangement, comprising:

(a) a bag within which a sample is collected;

(b) a tube being in fluid communication with the bag;

(c) a needle in fluid communication with the tube;

(d) an elbow pipe having an internal volume and an aperture, said elbow pipe being arranged and configured for operative connection to a closed fluid flow line from which a fluid sample is to be taken;

(e) a removable septum positioned within the aperture, the septum constructed for penetration of the needle therethrough to provide fluid communication between the internal volume of the elbow pipe and the bag.

2. The sampling arrangement of claim 1, wherein the aperture is positioned adjacent to a non-laminar fluid flow region of the elbow pipe.

3. The sampling arrangement of claim 1, wherein the septum comprises:

(i) a penetrable body;

(ii) a cap piece in contact with at least a portion of the penetrable body; and

(iii) a penetrable layer at least partially covering a portion of the cap piece.

4. The sampling arrangement of claim 3, wherein the penetrable body comprises a rubber construction.

5. The sampling arrangement of claim 3, wherein the penetrable body comprises a silicon construction.

6. The sampling arrangement of claim 3, wherein the penetrable body defines a volume of mass having a tapering diametric shape, the diameter proximate the cap piece corresponding to the diameter of the aperture of the elbow pipe.

7. The sampling arrangement of claim 3, wherein the septum includes an integral cap piece and penetrable body construction.

8. The sampling arrangement of claim 3, wherein the tubing is in fluid communication with the internal volume of the elbow pipe by insertion of the needle through the penetrable body of the septum.

9. The sampling arrangement of claim 3, wherein the cap piece includes a plurality of openings configured to guide the needle into the penetrable body of the septum during needle insertion.

10. The sampling arrangement of claim 9, wherein the plurality of openings is at least partially covered by the penetrable layer, the penetrable layer providing a visible indication of previously penetrated openings.

11. The sampling arrangement of claim 1 wherein the aperture includes an outwardly extended portion defining an internal diameter sized to receive the septum.

12. The sampling arrangement of claim 11 wherein the aperture further includes a male threaded section on the outwardly extended portion, and a threaded nut sized to cooperatively engage the male threaded section to secure the septum within the extended portion of the aperture.

13. The sampling arrangement of claim 1, wherein the elbow pipe includes coupling ends, each coupling end having a flange that further defines a groove to receive a sealing member, wherein the elbow pipe configuration is configured to retrofit within an existing fluid transportation system.

14. The sampling arrangement of claim 1, wherein the arrangement further includes a flow control device to regulate the fluid flow from the elbow pipe to the bag.

15. The sampling arrangement of claim 14, wherein the flow control device includes a clamp to restrict fluid flow to the bag.

16. The sampling arrangement of claim 14, wherein the flow control device includes a peristaltic pump to regulate fluid flow to the bag.

* * * * *

EXHIBIT B

US007044010B2

(12) **United States Patent**
Bigalke

(10) **Patent No.: US 7,044,010 B2**
(45) **Date of Patent: May 16, 2006**

(54) **CONTINUOUS FLUID SAMPLER AND METHOD**

(76) Inventor: **Darrell Lee Bigalke**, 11395 Irish Ave. North, Stillwater, MN (US) 55082

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **10/993,800**

(22) Filed: **Nov. 19, 2004**

(65) **Prior Publication Data**

US 2005/0066750 A1 Mar. 31, 2005

Related U.S. Application Data

(62) Division of application No. 10/022,294, filed on Dec. 14, 2001, now Pat. No. 6,845,676.

(51) **Int. Cl.**
G01N 1/14 (2006.01)
G01N 33/04 (2006.01)

(52) **U.S. Cl.** **73/863.03**; 73/863.85; 119/14.14

(58) **Field of Classification Search** 73/863.83–863.86, 863.03, 863.02, 864.34, 73/864.35; 119/14.14
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,534,613	A	10/1970	Travor et al.	73/863.85
3,776,042	A	12/1973	Werra et al.	73/863.85
3,779,082	A	12/1973	Galloway	73/863.85
4,785,676	A	11/1988	DeOca et al.	73/863.85
4,941,517	A	7/1990	Galloway	73/863.85 X
5,049,492	A	9/1991	Sauer et al.	73/863.85 X
5,086,813	A	2/1992	Galloway	73/863.85 X
5,119,473	A	6/1992	Ikenoue	
5,269,350	A	12/1993	Galloway	141/1
5,296,197	A	3/1994	Newberg et al.	73/863.85 X
5,743,209	A	4/1998	Bazin et al.	119/14.08
5,803,078	A	9/1998	Brauner	128/207.14
H1960	H	6/2001	Conrad et al.	73/864.83
2004/0228953	A1 *	11/2004	Bigalke	426/231

FOREIGN PATENT DOCUMENTS

WO	WO 96/03859	2/1996	
WO	WO 00/33901	6/2000	604/93

OTHER PUBLICATIONS

Exhibit A, "Keofitt World Leaders in Sterile Sampling", 4 pages (date unknown), but by Dec. 13, 2001.
Exhibit B, Liquid Sampling Systems, Inc., Cedar Rapids, IA, "The Pro-Rata™ Line Sampler, The future of dairy sampling-today", 4 pages, (date unknown), but by Dec. 13, 2001.
Exhibit C, Tate, J.L., "The Art of Managing Contamination", *Pharmaceutical Processing*, 4 pages (Jan. 2000).

* cited by examiner

Primary Examiner—Thomas P. Noland
(74) *Attorney, Agent, or Firm*—Merchant & Gould P.C.

(57) **ABSTRACT**

An aseptic, continuous sampling arrangement used in a fluid transportation system, the arrangement including an elbow pipe and a septum cartridge. The sampling arrangement further including a needle, a tube, and a collection reservoir, arranged such that the collection reservoir is in fluid contact with the fluid transportation system. The sampling arrangement configured to create a non-laminar fluid flow region from which a continuous sample of fluid material is drawn.

17 Claims, 5 Drawing Sheets

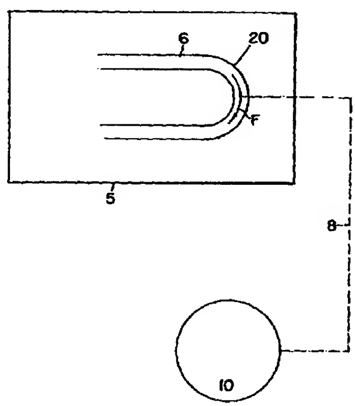
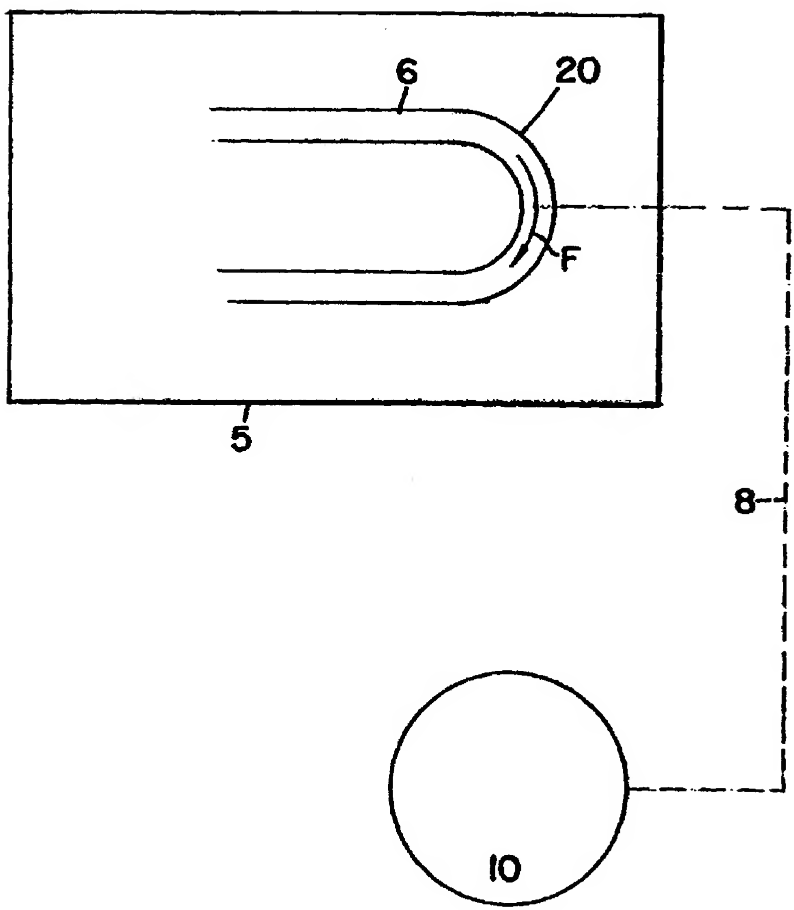


FIG. 1



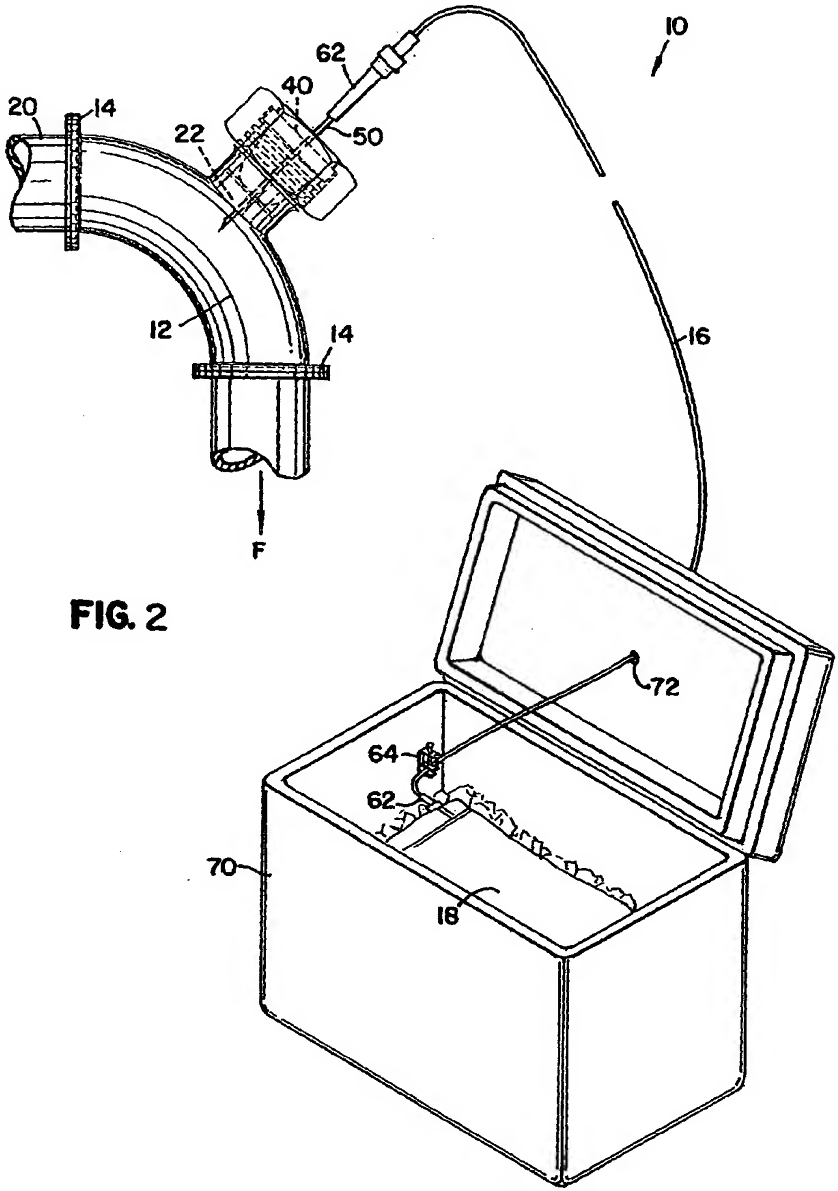
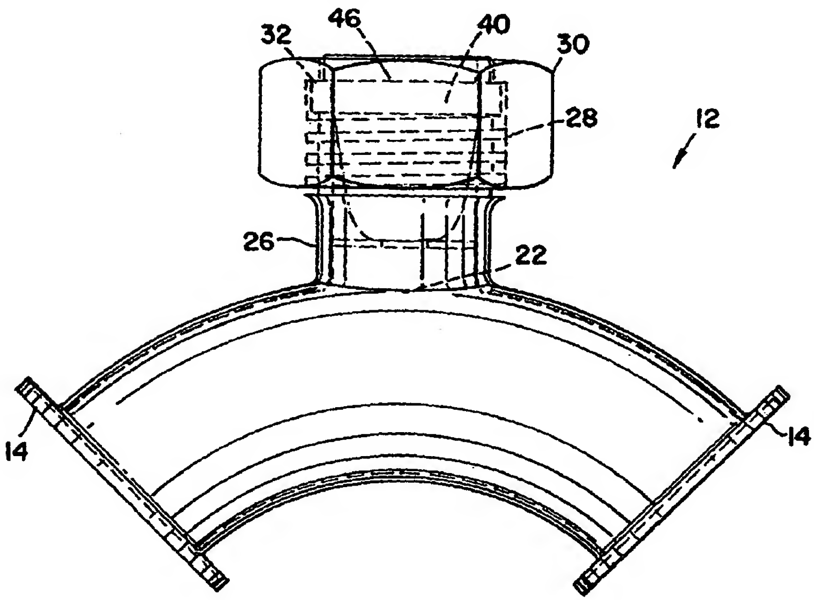


FIG. 2

FIG. 3



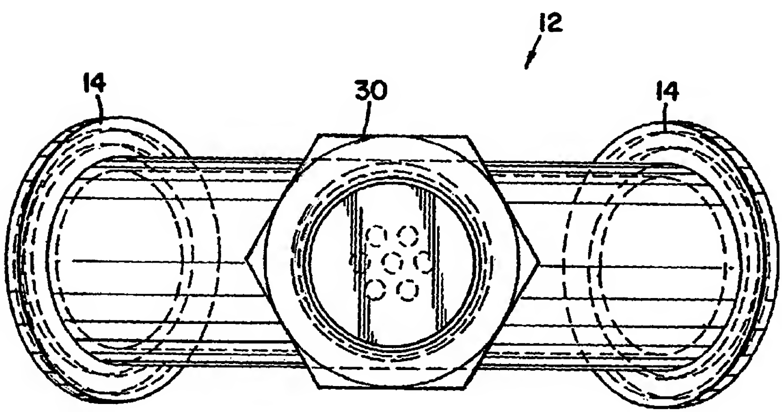


FIG. 4

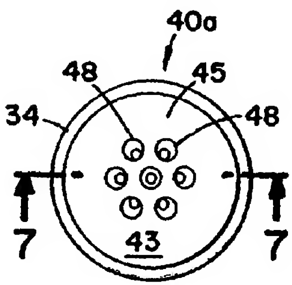


FIG. 5

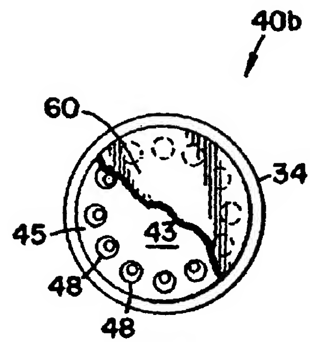


FIG. 6

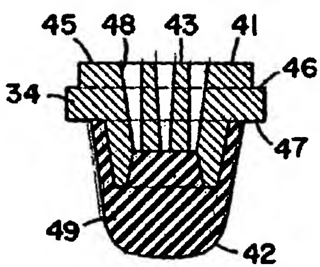


FIG. 7

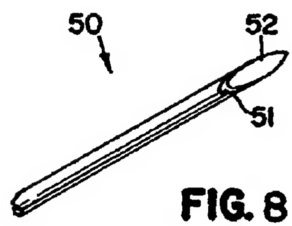
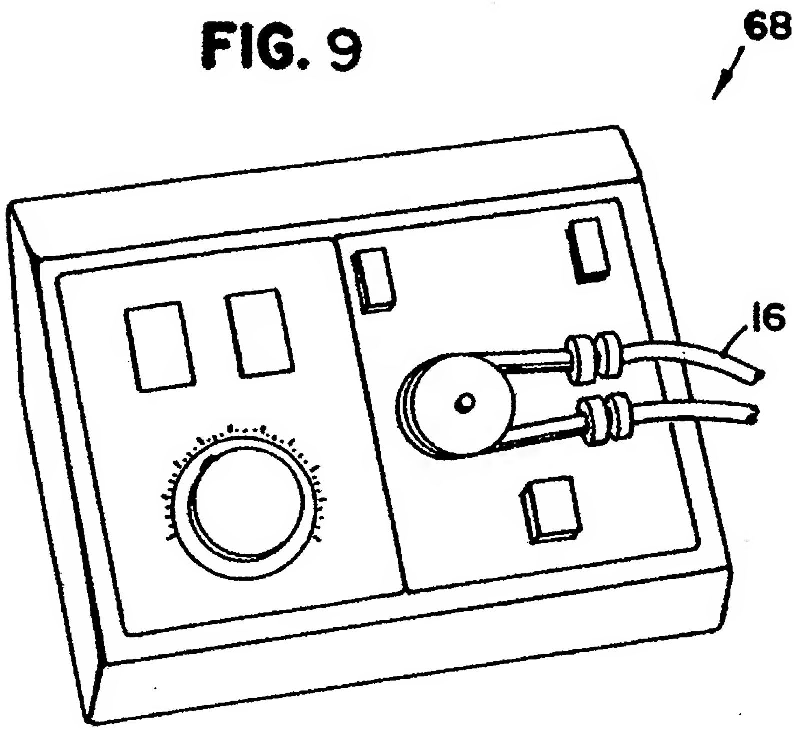


FIG. 8

FIG. 9



CONTINUOUS FLUID SAMPLER AND METHOD

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a divisional of application Ser. No. 10/022,294, filed Dec. 14, 2001 now U.S. Pat. No. 6,845, 676; which application is incorporated herein by reference.

FIELD OF THE INVENTION

This disclosure concerns a sampling arrangement. More specifically, this disclosure describes the assembly and method of use of a sampling arrangement for aseptic, continuous sampling of a fluid material.

BACKGROUND OF THE INVENTION

There are numerous applications wherein it is desirable to obtain discrete or continuous samples from fluid transportation systems or fluid processing enclosures. Enclosures and fluid transportation systems, as used herein, refer to any closed containment structure without respect to its size. Thus it includes such small enclosures such as cans that may be used in shipping starter bacteria from a culture lab. On the other end of the spectrum, it includes large tanks and associated pipelines, which may have capacities of several thousand gallons, such as are used in the dairy processing industry.

Efficient and effective techniques and apparatus for obtaining aseptic samples from such systems and enclosures, are particularly desirable. Examples of industries that require such aseptic sampling include, but are not limited to, the pharmaceutical, bioengineering/biotechnology, brewing/distilling, food processing and dairy processing industries. Applications for such samplings range broadly from process monitoring to laboratory and research applications. For example, sampling is commonly used on dairy farms for herd management or in regulated manufacturing facilities. The sampling is used to detect and control microbial contamination, spoilage microorganisms, food-borne illness, and environmental mastitis both within systems being sampled and externally of such systems. While preferred embodiments of this invention will be described with respect to its sampling use and application in the dairy industry, it will be understood that the invention is not to be construed as limited to use in that industry or to the application described, or to any limitations associated with the specifics of the components or methods disclosed with respect to such preferred embodiments.

Various methods and devices have been employed to perform sampling tasks. Typical sampling techniques commonly involve discrete or isolated sampling from a laminar portion of a fluid transport line. Typical such sampling systems and techniques that have been used in the dairy processing industry are described in U.S. Pat. Nos. 4,941, 517; 5,086,813; and 5,269,350. To the extent that such patents may be used to assist the reader in understanding principles and examples of sampling apparatus and methods, they are herein incorporated by reference.

While the apparatus and techniques described in these patents are particularly applicable to systems designed to accommodate them, there also exists a need to perform sampling in existing enclosures and fluid transportation systems that have not been designed for sampling functions.

Such systems typically require redesign or retrofitting to accommodate sampling functions. Such retrofitting can be expensive and/or difficult to achieve, can require significant system downtime in implementation of the sampling function and/or replacement of parts to maintain the system, or can lead to system degradation or contamination of the system being sampled. For example, one known method of discrete sampling of fluid involves inserting a needle through a sealing gasket located between connecting ends of pipelines of the fluid transportation system. Problems arises from this method as this method is not aseptic because the gasket becomes so perforated after repeated sampling that the gasket may lose its sealing integrity or introduce contaminants into the system though the perforations. This method requires that the gasket be replaced, which can become expensive both in labor costs and shut down costs.

There are many applications wherein it is desirable to obtain a continuous sample from fluid transportation systems or fluid processing enclosures. The discrete sampling methods typically extract a discrete sample size limited to the volume of a hypodermic needle and syringe. Typically the needle is inserted, fluid is drawn, and the needle is removed. It would be beneficial in some applications to have a system that could draw a continuous, controlled and constant sample volume over an extended period of time. A sampling device that facilitates this feature would also need to accommodate larger volume samples and a means to cool the sample during longer sampling time periods. While continuous sampling techniques have been tried, they have generally not been particularly effective, efficient or reliable in maintaining the aseptic condition of the system during the sampling interval.

Known discrete sampling techniques have not proven to be readily adaptable to continuous sampling techniques. For example, if the sample is taken from a region of laminar fluid flow, the sampling needle can create a venturi effect in the fluid flow being sampled, which can cause reverse flow siphoning from the collected sample and back into the sampled fluid. If such suction effect is disrupted by providing the sampling system with an air gap, the aseptic nature of the sampling system is compromised.

Improvement in methods and devices for sampling is needed, generally to better accommodate: ease of repeated continuous sampling of large volumes; structural integrity of fluid transport equipment; management of contamination; and convenience of continuous and controlled volume sampling. The present invention addresses these and other needs for continuous sampling of fluid transportation systems or fluid processing enclosures.

SUMMARY OF THE INVENTION

The present invention provides an efficient, effective and reliable assembly and method for aseptic continuous sampling of a fluid material. The principles of this invention can be simply implemented with readily available materials and techniques that enable application of the invention to sampling equipment of original design, as well as to relatively simple and inexpensive retrofitting of existing fluid enclosures or fluid transportation systems. The principles of this invention can readily be implemented in kit form for retrofitting applications. Further, replacement of expendable parts for maintaining the sampling system can be readily and inexpensively achieved without costly system down time and by minimizing contamination to the sampled system.

In one aspect of the invention, the disclosure describes a continuous sampling arrangement including a collection

container, a connecting conduit in closed fluid communication with the collection container, a collector in fluid communication with the connecting conduit, a pipe elbow having an aperture, and a septum positioned within the pipe aperture. The septum is constructed to provide for penetration of the needle to facilitate fluid communication between the pipe elbow and the collection container.

In another aspect of the invention, the disclosure describes a continuous sampling arrangement configured to create a non-laminar flow area from which a continuous sample is drawn. A septum is placed adjacent the non-laminar flow area to facilitate penetration of a needle into the non-laminar flow area and provide fluid communication between the non-laminar flow area and a collection container.

In yet another aspect, a method for aseptic continuous sampling is disclosed wherein the principles described herein in a variety of embodiments are used in aseptic processes of sampling fluids.

In still another aspect, the invention relates to a kit that retrofits to existing fluid transportation systems or enclosures to permit aseptic continuous sampling according to the principles disclosed.

BRIEF DESCRIPTION OF THE DRAWINGS

Referring to the drawings wherein like numerals represent like parts throughout the several views,

FIG. 1 is a schematic illustration of a system incorporating a continuous sampling arrangement in accordance with the principles disclosed;

FIG. 2 is a detailed schematic illustration of one embodiment of the continuous sampling arrangement in accordance with the principles disclosed;

FIG. 3 is a side view of a pipe elbow depicted in the sampling arrangement of FIG. 2;

FIG. 4 is a top view of the pipe elbow depicted in FIG. 3;

FIG. 5 is a top view of one embodiment of a septum used in the sampling arrangement of FIG. 2;

FIG. 6 is a top fractional view of another embodiment of a septum used in the sampling arrangement of FIG. 2;

FIG. 7 is a cross sectional view of the septum shown in FIG. 5, taken generally along line 7—7 of FIG. 5;

FIG. 8 is a fragmentary perspective view of a needle depicted in the sampling arrangement of FIG. 2; and

FIG. 9 is an illustration of one embodiment of a regulating device that can be used in the sampling arrangement of the present invention.

DETAILED DESCRIPTION

This invention provides an apparatus and method for the continuous aseptic sampling of fluid material from a fluid transportation system or fluid processing enclosure 5, schematically illustrated in FIG. 1. A fluid material 6 to be sampled is illustrated as flowing through a fluid line 20 by the fluid flow arrow designation "F". A preferred sampling arrangement of the present invention is schematically illustrated at 10 and is depicted as operatively connected, by the dashed line 8, to sample the fluid material 6 (as hereinafter described in more detail).

The principles described herein for the sampling arrangement 10 can be used in various industries and in various applications where aseptic sampling of material is desired. Aseptic sampling involves transferring fluids to or from process systems that are sensitive to contamination from the outside environment. For example, the pharmaceutical, bioengineering/biotechnology, brewing/distilling, food processing and dairy processing industries are in need of aseptic sampling technology. Such sampling technology can be applied broadly, the applications ranging from process monitoring to laboratory and research applications. For example, the fluid processing enclosure or fluid transportation system 5 illustrated in FIG. 1 may comprise a dairy processing system used in the dairy industry. An example of one type of fluid processing enclosure or fluid transportation system 5 that has been used in the dairy processing industry is described in U.S. Pat. No. 5,269,350 and herein incorporated by reference. In such a system, the fluid material 6 therein may include raw milk or a processed milk product. The sampling arrangement 10 may be incorporated or retrofitted to the fluid transportation system 5 to provide continuous aseptic sampling for detecting microbial contamination or monitoring mastitis, coliform, food-borne illness bacteria, or spoilage bacteria in a dairy herd, for example.

While preferred embodiments of this invention will be described with respect to its sampling use and application in the dairy industry, it will be understood that the invention is not to be construed as limited to use in that industry or to the particular application described.

The Structural Components, Generally.

Referring to FIG. 2, the preferred sampling arrangement 10 depicted includes: an elbow 12 having flanges 14 and a port 22; a least one septum or septum cartridge 40 (shown in phantom); a connecting conduit 16; and a collection container 18. In general, the sampling arrangement 10 comprises an arrangement that provides for a continuous draw of fluid from a flow F within a fluid line 20, and deposits the fluid sample in the collection container 18 to provide the user with an accumulated process sample. It is to be understood that the fluid line 20 may comprise a variety of fluid transportation systems or fluid containment enclosures, and is not limited to pipe constructions. The collection container 18 may include a pouch, bag, reservoir, or other closed container of a typical construction and size, such as those used in the medical industry. In the illustrated embodiment, a medical type bag comprising a 2-liter collection pouch or bag is used. A variety of sizes and constructions of containers is contemplated.

As illustrated, the pipe segment or elbow 12 of the sampling arrangement 10 is in direct fluid communication with the fluid line 20 of the fluid transportation system. In accordance with the principles of the present invention, it is desirable to perform sampling from an area or region of non-laminar flow within the line 20. The elbow 12 provides a turbulent or non-laminar flow region within its interior flow cavity by its non-linear configuration. It is to be understood that there are other means of creating a non-laminar flow region within the fluid flow line, such as having a protrusion or device extending into the flowing fluid within a substantially straight portion of the fluid line. Therein fluid turbulence or non-laminar flow is formed downstream of the extending device or protrusion. Creation of a non-laminar sampling region eliminates the problem of reversed fluid flow from the sample to the main fluid line, which commonly occurs in devices and methods of the prior art.

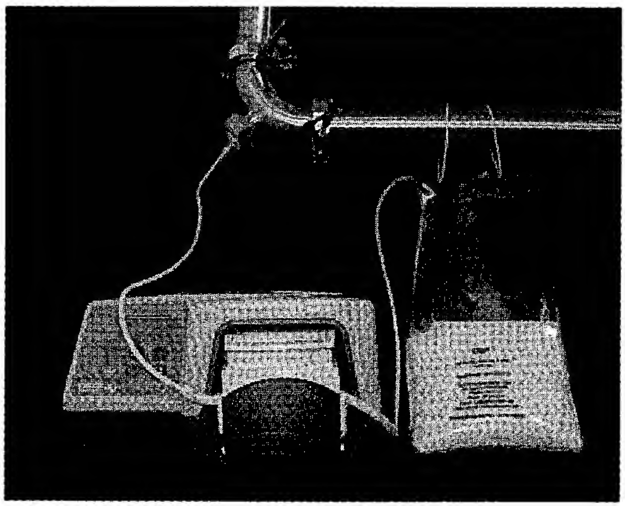
Referring now to FIGS. 3 and 4, the connection flanges 14 of the elbow 12 extend circumferentially at each end of the elbow 12. The flanges 14 may include grooves (shown in phantom) sized to receive sealing gaskets (not shown) to seal the connections between pipe segments when installed in common fluid transportation line systems. In accord with

has purposely availed itself to the benefit of doing business in the State of Minnesota by approaching QMI regarding a potential business relationship.

11. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400.

BACKGROUND FACTS

12. QMI is in the business of designing, manufacturing, distributing, and selling aseptic, user-friendly, cost-effective systems for sampling liquid processes. Such a system, as well as a method of using the system, is described and claimed in the '676 patent and is depicted below.



13. As depicted in the image above, the sampling system includes an elbow pipe with an aperture permitting continuous sampling of the liquid flowing through the elbow pipe. The system also includes a conduit through which the collected sample is passed, a pump which regulates flow through the conduit, and a bag which stores the collected sample. When the bag is full, it must be removed and replaced with a new, empty bag.

the principles of the present invention, the sampling arrangement is generally adapted to be retrofit within existing fluid lines of various fluid flow systems 5 (FIG. 1). Certainly the sampling arrangement **10** can be incorporated as original equipment into new installations of fluid transportation lines as well. Other means of connection or retrofit adaptation, including welding, are contemplated as a means of installation. The sampling arrangement is generally designed with standard plumbing components to facilitate retrofit modifications. It is to be understood that non-standard elements, such as non-standard pipe diameter, fittings, or material, are within the scope of the principles disclosed.

Preferably the elbow **12** is made of industry standard stainless steel, such as 304 or 316L stainless steel. Other materials applicable for use in the industry into which the sampling arrangement is implemented are contemplated. The elbow depicted in FIG. **3** incorporates a standard 90-degree elbow. The angular configuration of the elbow will typically be a standard dimension within the range of 35 degrees to 180 degrees, typically 90 degrees. The preferred diameter of the elbow pipe is at least 1 inch, typically from about 1.5 to 3.5 inches in diameter.

The elbow **12** according to the present invention includes at least one aperture or port **22**. The elbow **12** may be located in any configuration in the fluid transportation system where the port **22** is operably in fluid communication with the fluid material **6** within the system. Thus, the interior angle of the elbow **12** may be oriented, for example, upward, downward or sideways in a fluid line arrangement. It is also contemplated that to ensure that the port is operably in fluid communication with the fluid material **6**, the port **22** may be configured in alternative locations on the elbow **12**. In the illustrated embodiment, the port **22** is located on the outer radius of the elbow **12**. Alternative embodiments may include, for example, an elbow having a port located on the interior radius of the elbow. Preferably, the port **22** is disposed at or within a non-laminar flow region of the elbow **12**.

As depicted in FIG. **3**, the port **22** may include a transversely extending pipe portion or conduit **26**. The conduit **26** is sized to receive a septum cartridge **40**. The conduit **26** may include an externally threaded region **28** for purposes of securing the septum cartridge **40**. In one embodiment, the thread comprises a standard 1.5"—8 ACME thread corresponding to a mating internally threaded nut **30**. The threaded nut **30** may include an internal annular shoulder **32** (shown in phantom). The annular shoulder **32** acts as a bearing surface that engages a first surface **46** of the septum cartridge **40** (shown also in FIG. **7**) to secure the septum cartridge in sealing manner when assembled within the port **22**. Other types of fasteners commonly used as securing or retaining means within this context are contemplated and may include, for example, a hex nut, a knurled lock nut, or a keyed nut.

Referring generally to FIG. **2**, the septum cartridge **40** is in fluid communication with the interior cavity of the fluid line **20** by means of the aperture or port **22** in the elbow **12**. As shown in FIGS. **5**–**7**, the septum cartridge **40** generally comprises a cap **45**, a central core member or boot **49**, and a plurality of guide holes **48** formed through the cap. For purposes of clarifying features, the septum cartridge **40** can be considered to have a top **41** and a bottom **42**.

The cross-section of the boot **49** is seen to increase progressively from the bottom **42** toward the top **41** of the septum cartridge **40**. The boot **49** is sized such that when the boot is placed within the port **22** of the elbow there is compressive contact between the interior surfaces defining the port **22** and the boot **49**. The boot thereby functions as a sealing member. The boot **49** illustrated is generally conical, but could adopt a variety of shapes as will be obvious from the following discussion of the functioning of the septum cartridge in combination with other components of the invention.

The boot **49** may be made of material that is generally considered to be of a rubber compound. While compounding of an acceptable rubber composition is believed to be within the skill of the rubber molding art, it is found that rubber compounds based on ethylene propylene diene monomer terpolymer (EPDM) are particularly advantageous, having suitable sealing characteristics. EPDM is a known elastomer, and recognized by those skilled in the polymer arts. Other elastomers are contemplated, such as those derived from, or modified with, butene isoprene, ethylene, and the like. In an alternative embodiment, the boot may comprise a silicon compound. Silicon also provides suitable sealing characteristics. Materials such as Viton or other FDA approved elastomers are also contemplated for use in manufacture of the boot.

Preferably, the cap **45** includes an annular radially extending portion **34** defining the first upwardly oriented surface **46** and an opposing second lower surface **47**. The outer diameter of the annular portion **34** is preferably only slightly less than the inner diameter of the internal shoulder **32** on the threaded nut **30** for purposes of engaging and retaining the septum cartridge **40** within the port **22** of the elbow in the sampling arrangement **10**.

The cap **45** is made of a material that is normally not penetrable by conventional hypodermic needles. A typical material for fabrication of the cap may include one of the engineering plastics, such as nylon, polypropylene, or high-density polyethylene. The penetrability of the septum cartridge **40** is thus provided by one or more of the integrally formed guide holes **48**, which begin from a top surface **43** of the cap **45** and extend downwardly through the cap **45**.

The guide holes **48** are integral with the cap **45** and located to correspond to the boot **49**. The guide holes **48** extend downwardly through the cap structure **45** and are oriented and positioned so that a sampling needle **50** (shown in FIG. **8**) may pass through the guide hole **48** and into the boot **49**. The guide holes **48** are generally sized to be only slightly larger than the needle, such that the needle slidably fits snugly within the guide hole, preferably without substantial friction, but with a close enough fit to ensure that the guide hole provides direction to the needle as it is inserted through the boot. In one embodiment (FIG. **5**), the septum cartridge **40*a*** includes seven guide holes. In another embodiment (FIG. **6**), the septum cartridge **40*b*** includes twelve guide holes. Typically the septum cartridge includes at least one guide hole, generally 1 to 15 guide holes.

A cover film **60** covers the top surface **43** of the cap **45**, including the guide holes **48** formed in the top surface **43** of the cap **45**. The cover film **60** easily identifies used holes to reduce the risk of contamination from reinserting a needle into a previously used guide hole. The cover film **60** may be made from any readily pierceable film material. A typical film material is a vinyl tape having an adhesive coating to securably attach the cover film **60** to the top surface of the cap **45**.

Referring to FIGS. **2** and **8**, the penetrating body or needle **50** is in fluid communication with the connecting conduit **16**, and the connecting conduit **16** is in fluid communication with the collection container **18**. In the preferred embodiment, the needle comprises a beveled end **51** having an aperture **52** that defines a hollow portion running longitu-

dinally through the needle **50**. It is to be understood that other penetrating bodies, such as lumens, hollow members, or inserting devices may be used in accordance with the principles disclosed.

In use, the needle **50** penetrates the cover **60**, passes through a selected guide hole **48**, and penetrates through the boot **49**. As the needle penetrates the boot, the needle displaces the elastomeric/rubber material of the boot which forms a fluid impenetrable seal about the needle. The beveled end **51** of the needle **50** progresses through the boot **49** and emerges from the boot at the bottom **42** of the septum cartridge **40**. The needle therein enters into the flow of fluid F.

The needle **50** is sized and adapted for use with the septum cartridge **40**. Typically the needle comprises a 12 gauge to 22 gauge needle, preferably a 16 gauge needle. The needle generally has a length of from about 1.0 inches to 4.5 inches. Preferably the needle is at least 1.5 inches in length if the port **22** is bottom placement oriented and at least 2.0 inches if the port **22** is top placement oriented. What is meant by top and bottom placement oriented is how the sampling port is oriented with respect to ground. Thus, if the elbow is top placement oriented, a longer needle **50** is needed to ensure the needle aperture **52** is submerged within the fluid material when operatively inserted through the septum **40**.

Still referring to FIG. 2, the connecting conduit **16** also includes sealing ends **62** at locations where the fluid flow transitions from the needle **50** to the connecting conduit **16** and from the connecting conduit **16** to the collection container **18**. A typical, usable connecting conduit is the type used by the medical industry in fluid administration sets. Conduit in accordance with the principles disclosed includes, for example, tubing, flexible piping or flexible lumen constructions that provide closed, aseptic fluid communication between ends.

Preferably the connecting conduit **16** is of sufficient length to reach from the elbow **12** to an area where the collection container **18** is placed. The length may thus vary and typically falls within the range of 5 inches to 65 inches, and preferably is about 38 inches in length. In one embodiment, the connecting conduit comprises a 0.121 inch inside diameter and a 0.166 outside diameter. It is to be understood that typical fluid administration sets having a needle, connecting conduit, and a collection pouch are contemplated for use in this sampling arrangement.

In use, the needle **50** is inserted through the septum **40** into a non-laminar fluid flow region of the elbow **12**. Sampling at a non-laminar fluid flow region addresses the problem of reversed fluid flow often created by a venturi effect of prior sampling systems. The venturi effect is created where the velocity of the laminar fluid flow flowing past an orifice or tube opening (such as in a needle) causes a corresponding decrease in fluid pressure, which creates a siphoning or suction. Thus, instead of drawing sampled fluid from the fluid line into a collection container, sampled fluid is actually drawn from the collection container back into the fluid line. The sampling arrangement **10** of the present invention reduces or eliminates this problem.

Some Selected Alternate Embodiments

Alternative embodiments incorporating the principles of the present invention will be apparent from the description below and in the context of the illustrations in FIGS. 2 and 9.

In one alternative embodiment, the sampling arrangement **10** includes a flow restricting device. The flow restricting device may comprise a clamp **64** as shown in FIG. 2. The clamp **64** compressively engages the outer surface of the connecting conduit **16** and is adjustable such that flow through the tube may be restricted to a desired flow rate. Thereby, the continuous sampling rate may be increased or decreased during sampling as needed.

Another embodiment of the sampling arrangement includes an alternative means of regulating flow. FIG. 9 depicts a fragmented portion of a sampling arrangement including a metering or peristaltic pump **68**. The peristaltic pump **68** cooperatively engages connecting conduit **16** and is adjusted as is known in the art to provide a desired regulated flow rate.

The clamp **64** and the peristaltic pump **68** are products of common manufacture. The clamp may comprise any clamping device suitable to provide restriction in the connecting conduit **16**. The peristaltic pump may comprise, for example, a variable flow pump having a medium flow rate of 4.0 to 85.0 milliliters per minute. Specifically, a Medium Flow variable flow pump, Model Number 54856-075, manufactured by MASTERFLEX is one variable flow pump that may be used.

Yet another embodiment of the present invention provides for cooling of the extracted sample held by the collection container. If it is desirable to keep the extracted sample cool during collection, the collection container **18** may be placed in an insulated cooler **70** surrounded by ice or cold packs as shown in FIG. 1, for example. Common coolers can be modified to include a hole **72** in the top or lid through which the connecting conduit **16** can be routed.

The alternative embodiments herein described may be used in combination with each other or used independent of one another.

The Method of Continuous Sampling, Generally.

In operation, the elbow **12** is installed at a convenient sampling location along a fluid line **20**. The elbow is preferably oriented such that the port **22** is in direct fluid contact with the material transferred within the fluid line, to reduce the potential of air drawn during sampling.

The boot **49** of the septum cartridge **40** is placed into the sampling port **22** until the second surface **47** of the cap **45** rests against the outer edge of the sampling port **22**. The securing nut **30** is installed onto the conduit of the port **22** to sealingly, operatively secure the septum within the port.

For aseptic sampling, the sampling arrangement, including the port, nut, septum cartridge, etc, are sanitized with a common alcohol prep or other sanitizer. In particular, aseptic sampling is optimized when the cover film **60** is cleansed with a disinfectant, and a sterilized needle **50** is inserted through the disinfected cover film, through an unused guide hole, and through the septum boot.

The needle is preferably directed or slanted toward the center of the septum boot at insertion. This provides greater assurance that the needle penetrates through the entirety of the boot. In effect, the boot essentially squeegees or cleanses the needle of any contaminants missed during initial aseptic disinfectant processes. Directing the needle toward the center of the boot also reduces the possibility of contacting the wall of the extended portion of the elbow.

The needle may be oriented such that the beveled end **51** faces toward the flow of the fluid material to aid in fluid sampling. A pressure differential is applied between the collection container and the fluid line to effect the fluid sampling or material transfer. The pressure differential maybe applied in a number of ways. One way is by introducing pressure into the fluid line. Another is by reduc-

ing pressure in the connecting conduit or collection container. Any means of generating an adequate pressure differential between the fluid line and the collection container is effective to cause the flow of material through the needle. Other methods of applying the pressure differential and thus effecting the transfer of a sample will be obvious to those skilled in the art.

Material from a tank, for example, thus flows from the fluid line **20**, through the needle **50**, and into the collection container **18** by way of the connecting conduit **16**. In one alternative application, the collection container may be placed into a cooling container **70** of ice or ice water, for example, to reduce or eliminate bacterial growth during the sampling process.

The flow from the fluid line **20** to the collection container **18** may be adjusted to a particular flow or sampling rate by means of the clamp restriction. The flow may likewise be metered wherein the peristaltic pump is assembled to the connecting conduit to regulate the flow.

When the desired sample has been collected, the collection container is removed from the connecting conduit **16** and sealed. The needle **50** is removed from the septum cartridge **40**. As the needle end is withdrawn, the material of the boot **49** withdraws into the position held prior to needle penetration. The boot **49** of the septum **40** thus closes and seals the passageway of the now removed needle.

After performing a number of sampling procedures, so that all guide holes have been used, the septum cartridge **40** is removed and discarded. The punctured cover film **60** provides a ready indictor of those guide holes that have been used. A new septum cartridge easily replaces the used septum cartridge for future samplings.

The above specification, examples and data provide a complete description of the manufacture and use of the invention. Many embodiments of the invention can be made according to the disclosed principles.

I claim:

1. A method of continuous aseptic sampling, comprising the steps of;

(a) providing a fluid transportation structure that creates a non-laminar flow of a fluid in a sampling area within a fluid transportation system, the fluid transportation structure including an aperture located proximate the non-laminar sampling area;

(b) providing a replaceable septum to seal the aperture of the fluid transportation structure and prevent the introduction of contaminates into the sampling area, the septum including an outer surface area and a plurality of guide holes covered by a cover piece that provides indication of used guide holes and unused guide holes;

(c) providing a sterilized penetrating member, tubing, and a reservoir, wherein the penetrating member, tubing and reservoir are all in fluid communication with each other, the tubing and reservoir being sealed from environmental contaminates;

(d) performing aseptic cleansing of the outer surface area and cover piece of the septum;

(e) inserting the sterilized penetrating member into an unused guide hole wherein the guide hole directs the penetrating member into and through the septum, the septum constructed to further wipe and remove contaminates from the penetrating member during insertion; and

(f) creating a pressure differential between the reservoir and the fluid transportation structure such that a sampling fluid continuously flows from the fluid transportation structure to the reservoir.

2. The method of claim **1**, wherein the method of continuous aseptic sampling includes removing the penetrating member from the septum upon obtaining a sufficient sample size, the septum functioning to re-seal the sampling area to prevent entry of contaminates into the sampling area after removal of the penetrating member.

3. The method of claim **1**, wherein the method of continuous aseptic sampling includes monitoring fluid flow and controlling flow rate by selectively introducing or increasing a restriction on the tubing.

4. The method of claim **3**, wherein controlling the flow rate by introduction of a restriction is accomplished by use of a clamp.

5. The method of claim **3**, wherein controlling the flow rate by introduction of a restriction is accomplished by use of a peristaltic pump.

6. A method of continuous aseptic sampling, comprising the steps of:

(a) providing a fluid transportation structure having a portion configured therein to create a non-laminar fluid flow in a sampling region, and providing a sampling assembly having a penetrable member positioned in an opening located in the sampling region; and

(b) obtaining an aseptic, continuous fluid sample from the non-laminar fluid flow in the sampling region, while simultaneously sealing the sampling region.

7. The method of claim **6**, further including collecting the fluid sample from the non-laminar fluid flow in a collection reservoir.

8. The method of claim **7**, further including cooling the fluid sample collected in the collection reservoir.

9. The method of claim **7**, wherein the step of collecting the fluid sample in the collection reservoir includes extending a length of tubing between the penetrable member and the collection reservoir, and creating a pressure differential between the collection reservoir and the fluid transportation structure to provide aseptic, continuous fluid communication between the fluid transportation structure and the collection reservoir.

10. The method of claim **6**, further including retrofitting an existing fluid transportation system with the fluid transportation structure having the portion configured to create the non-laminar fluid flow.

11. The method of claim **10**, wherein the step of retrofitting includes fitting a pipe having an aperture and an angular configuration to the existing fluid transportation system such that fluid from the system flows through the pipe.

12. The method of claim **11**, further including securing the penetrable member within the aperture of the pipe.

13. The method of claim **6**, wherein the step of obtaining a continuous, aseptic fluid sample includes inserting a sampling body into and through the penetrable member to contact the non-laminar fluid flow created in the sampling region.

14. The method of claim **6**, wherein the step of obtaining the aseptic, continuous fluid sample from the non-laminar fluid flow in the sampling region includes obtaining a milk sample from a milk processing system.

15. The method of claim **14**, further including detecting microbial contamination in the milk sample for purposes of dairy herd management.

16. The method of claim **14**, further including testing the milk sample for the purpose of monitoring mastitis in a dairy herd.

17. The method of claim **16**, further including regulating the rate of the fluid sample collection with a flow control device.

* * * * *

EXHIBIT C

BoldBioTech

Disposable Bag Systems and Devices for the Microbiology, Pharmaceutical, and Biotechnical Industries

Contact Us

BoldBioTech, Inc
Fernandina Beach, FL
(904) 556-1801

Amarillo, TX
(800) 372-5489

Email:
sales@boldbiotech.com

Products

Click Here to View BoldBioTech's standard available product line.

Prices

Call today for a custom quote to meet your individual sampling needs.

Events

Visit us at:

New Mexico Agricultural Expo

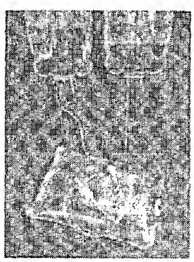
February 23 & 24, 2010
Portales, New Mexico

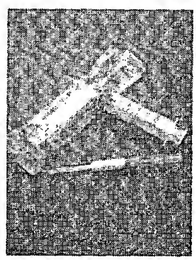
Aseptic Sampling
Product Collection
Fluid Transfers
Sterile Storage
Media Growth
Dairy Composite Samples
Food Sciences
Quality Control Kits

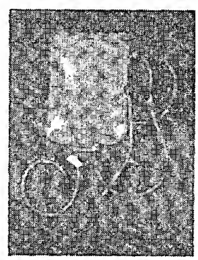
Our LOW COST single use sterile bags and devices are designed for various applictions.

Boldbiotech LOW COST QUALITY single use sterile bags, kits, and systems are designed for aseptic sampling, product collection, sterile fluid transfers, media storage, and any other application where sterile fluid quality control is required.

Our products are manufactured in various sizes and can be configured to meet your specific requirements. Products and systems are developed in accordance with company quality assurance standard operating procedures which meet Good Manufacturing Practices (cGMP). Certificates of Compliance and Processing are always available. Sterile products are gamma processed by using properly tested specific standard doses.







Boldbiotech kits and bags are used to collect blood, milk, water, serum, processed fluids, waste, liquid food products, beverages, etc. Boldbiotech systems are used in the microbiology, dairy, waste water, liquid processing, winery, brewery, food safety, and many other industries that need to control and identify contamination. Boldbiotech

manufactures a LOW COST premium bag that is an original equipment replacement collection container for use with the QMI® aseptic sampling system, Smart Gasket® in-line sampling system, and many other in-line sampling methods requiring an aseptic collection device. At sometimes half the price and enhanced aseptic usefulness these bags are a GREAT VALUE.

Management has over fifty years of combined experience in the biotechnology collection and manufacturing industry. We can help with your engineering and design needs. We have developed and maintain a strict quality compliance policy. Our quality control systems assure all products meet customer specifications and comply with all applicable regulations regarding the quality of our products. The purpose of these quality compliance policies is to promote a high standard of excellence in our products while documenting procedures for customer satisfaction. These policies are reviewed periodically by management and changed when necessary to improve production, methods, and quality.

Copyright © BoldBioTech, Inc. All rights reserved.
Tel: 800.372.5489 / Email: sales@boldbiotech.com

JS 44 (Rev. 12/07)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS	DEFENDANTS
Quality Management, Inc.	Tom W. Thurman, Inc. d/b/a BoldBio Tech., Inc.
(b) County of Residence of First Listed Plaintiff Washington (EXCEPT IN U.S. PLAINTIFF CASES)	County of Residence of First Listed Defendant Potter (IN U.S. PLAINTIFF CASES ONLY) NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.
(c) Attorney's (Firm Name, Address, and Telephone Number) Christopher J. Sorenson, Merchant & Gould P.C. 80 South 8th Street, Minneapolis, MN 55402 (612) 332-5300	Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant) (For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated or Principal Place of Business In This State	☒ 4	☐ 4
Citizen of Another State	☐ 2	☒ 2	Incorporated and Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury - Med. Malpractice
- ☐ 365 Personal Injury - Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt.Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☒ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN (Place an "X" in One Box Only)

- ☒ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from another district (specify)
- ☐ 6 Multidistrict Litigation
- ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
28 U.S.C. § 1331 and 1338(a)

Brief description of cause:
Inducing Patent Infringement

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND $ Unspecified

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE DOCKET NUMBER

DATE
03/25/2010

SIGNATURE OF ATTORNEY OF RECORD
s/Christopher J. Sorenson

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

14. QMI sells replacement bags for its customers to use with the sampling systems these customers have purchased from QMI.

15. QMI labels each of its bags with a mark reading "Patent Number: US 6,845,676 B2."

16. In or around 2007, Defendant approached QMI with the hope of becoming QMI's supplier of replacement bags. QMI requested sample bags from Defendant, which Defendant provided. After analyzing the sample bags, QMI had concerns regarding the quality of the bags and asked Defendant to provide validation data demonstrating that the bags were capable of aseptic sample collection. About this time, discussion between Defendant and QMI ceased.

17. Rather than sell these bags to QMI, Defendant now sells its replacement bags directly to end users through its website (http://www.boldbiotech.com). A printout of this website is attached as Exhibit C.

18. On its website, Defendant specifically instructs potential customers to use Defendant's replacement bags with sample collection systems sold by QMI: "Boldbiotech manufactures a LOW COST premium bag that is an original equipment replacement collection container for use with the QMI® aseptic sampling system . . . ." (*See* Exhibit C.)

19. By encouraging consumers to use the Defendant replacement bags with QMI systems, Defendant is encouraging consumers to use a system covered by the '676 patent and practice a method covered by the '010 patent with products not manufactured, distributed, sold, approved, or endorsed by QMI.

INDUCING INFRINGEMENT OF THE '676 PATENT (Count I)

20. The allegations of the preceding paragraphs 1-19 are repeated and incorporated herein by reference.

21. On January 25, 2005, United States Patent No. 6,845,676 entitled CONTINUOUS FLUID SAMPLER AND METHOD was duly and legally issued to QMI as assignee; and since that date QMI has been, and still is, the owner of all right, title, and interest in the '676 patent.

22. Defendant encouraged or instructed customers and potential customers to use a product that infringes the '676 patent claims through the sale of Defendant's replacement bags and instruction to use said bags with QMI sampling systems.

23. Defendant knew of the '676 patent.

24. Defendant knew that its encouragement or instructions would likely result in its customers infringing the claims of '676 patent.

25. Defendant's customers directly infringe the '676 patent.

26. QMI has been damaged by Defendant's inducement of infringement of the '676 patent and will continue to be damaged in the future unless Defendant is permanently enjoined from inducing its customers from infringing said patent.

27. QMI complies with the notice provision of the patent statutes by marking its goods with the patent number.

28. Defendant is aware that the '676 patent was duly and legally issued and that the use of Defendant's customers of Defendant's replacement bags infringes said patent.

29. Defendant's inducement of infringement of the '676 patent has been willful and will continue unless enjoined by the Court.

INDUCING INFRINGEMENT OF THE '010 PATENT (Count II)

30. The allegations of the preceding paragraphs 1-29 are repeated and incorporated herein by reference.

31. On May 16, 2006, United States Patent No. 7,044,010 entitled CONTINUOUS FLUID SAMPLER AND METHOD was duly and legally issued to QMI as assignee; and since that date QMI has been, and still is, the owner of all right, title, and interest in the '010 patent.

32. Defendant encouraged or instructed customers and potential customers to perform a process that infringes the '010 patent claims through the sale of Defendant's replacement bags and instruction to use said bags with QMI sampling systems.

33. Upon information and belief, Defendant knew of the '010 patent.

34. Upon information and belief, Defendant knew that its encouragement or instructions would likely result in its customers infringing the claims of '010 patent.

35. Upon information and belief, Defendant's customers directly infringed the '010 patent.

36. QMI has been damaged by Defendant's inducement of infringement of the '676 patent and will continue to be damaged in the future unless Defendant is permanently enjoined from inducing its customers from infringing said patent.

37. Upon information and belief, Defendant is aware that the '010 patent was duly and legally issued and that the use of Defendant's customers of Defendant's replacement bags infringes said patent.

Upon information and belief, Defendant's inducement of infringement of the '010 patent has been willful and will continue unless enjoined by the Court.

PRAYER FOR RELIEF

WHEREFORE, QMI prays for judgment that:

A. Defendant has induced infringement of United States Patent Nos. 6,845,676 and 7,044,010;

B. Defendant, its officers, agents, servants, and employees and those persons in active concert or participation with any of them be enjoined from further inducing infringement of United States Patent Nos. 6,845,676 and 7,044,010;

C. An accounting be had for the damages arising out of Defendant's inducing infringement of United States Patent Nos. 6,845,676 and 7,044,010, including treble damages for willful inducement as provided by 35 U.S.C. § 284, with interest;

D. Defendant be preliminarily and permanently enjoined from continued use, importation, offer for sale, or sale of Defendant's products in a way that induces infringement of the '676 patent and the '010 patent;

E. QMI be award its attorneys' fees, costs, and expenses in this action; and

F. QMI be awarded such other and further relief as this Court may deem necessary and proper.

DEMAND FOR JURY TRIAL

QMI hereby demands a trial by jury of all issues so triable.

Date: March 25, 2010

s/Christopher J. Sorenson
Christopher J. Sorenson (MN# 270188)
Eric R. Chad (MN# 388944)
MERCHANT & GOULD
3200 IDS Center
80 South Eighth Street
Minneapolis, MN 55402-2215
Telephone: (612) 332-5300
Facsimile: (612) 332-9081
csorenson@merchantgould.com
echad@merchantgould.com

Attorneys for Plaintiff Quality Management, Inc.

EXHIBIT A